

FMD Tutorial

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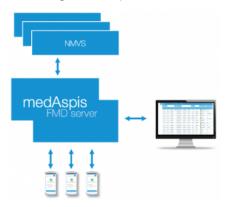
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1 The System Design

The medAspis system is essentially a server solution on which the functions of the FMD examination run. The data is delivered to the system with Speed Scanners.

The Speed Scanners are Android handheld devices that are connected to the Internet via WLAN or mobile data. The handheld devices communicate with the server via this channel. To ensure data security, communications between the devices and the server are encrypted. The HTTPS protocol is used for this purpose. To further ensure security, customers will be given ports and URL upon request to configure the respective firewall.



1.1 The basic design of the medAspis FMD system

As many handheld devices as required can be connected to the server. Communication between the devices is not necessary. Each device always communicates directly with the server.

The server is connected to the respective NMVS. Depending on the NMVS technology, different protocols are supported. With the Control Panel, a portal is available to monitor and control the system.



2 The User Interface

The medAspis system uses mobile handheld scanners to scan medicine packs on site. The device is called Speed Scanner. The scan results can be reviewed and further processed via the Control Panel web portal. The system can be booked in different expansion stages. The full expansion stage is described here.

2.1 The Speed Scanner

The Speed Scanner is a commercially available Android smart device with a scanner unit. The application described here runs on this unit. This application can be updated via the F-Droid application. This update can be done automatically or manually.

2.1.1 The User Interface of the Speed Scanner

The user interface is divided into different fixed areas.

2.1.1.1 In the middle of the screen:

The captured information of the last scan together with a timestamp is centrally located. Above this you will find the result of the check by the responsible NMVS. If the system transmits the product name, it is displayed here. This product name may be truncated if the name is too long for one line. A symbol indicates whether the result was positive (green tick) or negative (red cross). The Solidsoft system issues a warning with a yellow icon. Other warnings – for example after scanning a barcode with the wrong format – come with a blue symbol. A list of all the symbols is to be found in the attachment.

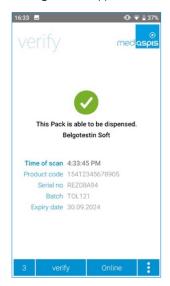
2.1.1.2 The lower control line:

On the left, in the lower corner, is a counter. This counter counts all scanned packs but ignores duplicate scans of the same pack. Clicking on the number resets it to zero.

To the right of the counter is the FMD menu. With this menu, the FMD operation can be selected. The last FMD operation selected remains until a new operation is selected. For better usability, the designation of the selected FMD operation is displayed repeatedly in the upper left-hand corner

The half-right display shows whether the unit is currently connected to the medAspis FMD system via the Internet.

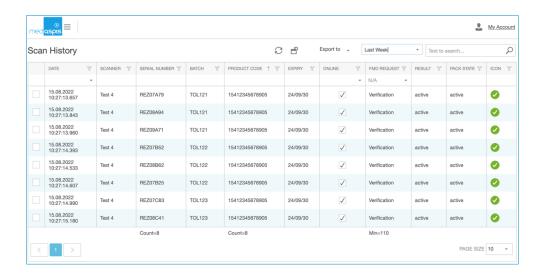
The three dots to the far right of it call up the settings for the application.





2.2 The Control Panel

The Control Panel is a web portal and is accessed via the address https://panel.medaspis.org. The Control Panel has a menu on the left side. By clicking on the three bars next to the medAspis logo, the menu can be folded away to make better use of the space on the screen. The Scan History is always displayed as the start screen. Other items in the menu are the scan archive and grouping (optional). The settings concern the organisation, the Speed Scanners used, access to the NMVS and a user administration for the Speed Scanners.





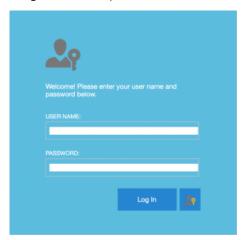
3 Setting up the System

3.1 Create an account

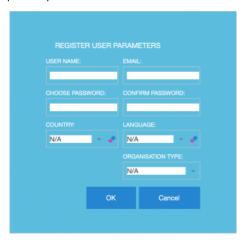
In principle, customers can register with medAspis themselves and manage their details.

3.2 Log on to the system

The medAspis system can be reached at https://panel.medaspis.org. A login field appears. In the lower right corner of the blue login field, click the button with the figure and the key.



Another window with registration requests opens.



The parameters requested for the registration process are:

USER NAME: Future access under this name

CHOOSE PASSWORD: Future password with high complexity

COUNTRY: According to this country specification, the competent NMVO is selected

EMAIL: Additional information on registration

LANGUAGE: Language used in Speed Scanner and Control Panel

ORGANISATION TYPE: Wholesale or pharmacy for system control



3.2.1 Password complexity

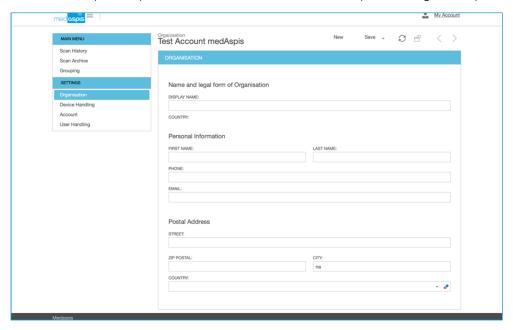
The password must not be too simple, it must be subject to a certain complexity. It is up to the user how to achieve this complexity. Basically, the following factors are included in the complexity calculation of the password:

- Password length
- Use of upper and lower case
- Use of special characters
- Use of digits

There is no rule that prescribes to use all the complexity elements mentioned above. A password can be complex enough if you do not use special characters, but the length of the password already forms a sufficient complexity.

3.3 Complete organisation

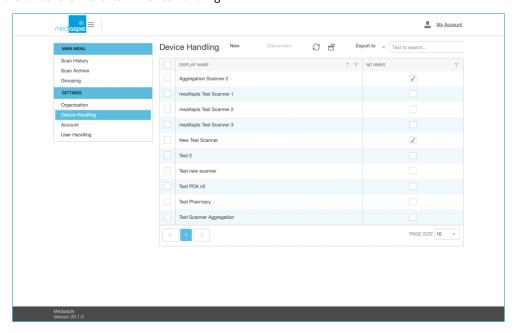
After entering this data, the control panel opens and further data of the organisation is requested. These are the name and address as well as a responsible person for further communication. This completes the registration process.





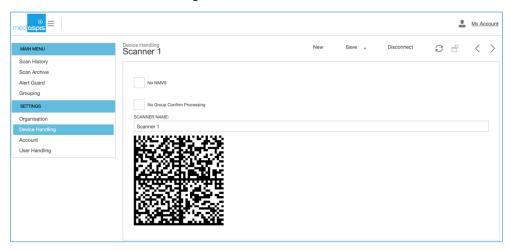
3.4 Setting up a Speed Scanner (server side)

Each Speed Scanner used must be logged into the customer account. To do this, a new device must be registered in the Control Panel under the menu item "Device Handling".



After opening the window, you can see all the scanners that have been registered so far. The scanners are displayed with their name and the parameter "No NMVS".

With the button "New" a new scanner can be registered.



Two fields must be specified for the new scanner:

NAME: The name of the scanner. This name is later visible in the Settings menu of the scanner

and the scans appear under this name in the Scan History.

NO NMVS: If this value is clicked, the scanned data is not transmitted to the NMVS. Customers use

this setting to read 2D matrix codes, but not to evaluate them via the NMVS.

No Group Confirm Processing Normally, once a group has been closed, no more packs can be added. Activating this

function drops this restriction. Groupings can be extended at any time.



The process is completed with the "Save" button. A large enrolment code appears on the screen. This must be read in by the Speed Scanner to be connected in the enrolment process in order to connect it to your own system.

Each scanner can be logged in and out of the system as required. To disconnect the scanner from the control panel, use the "Disconnect" button. New registrations are always made by entering a scanner in the scanner list of the menu item "Device Handling".

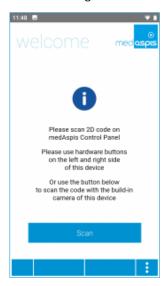
Once a scanner has been created, it cannot be deleted. This ensures that it is always possible to determine which data was read in with which scanner (data integrity, audit trail).

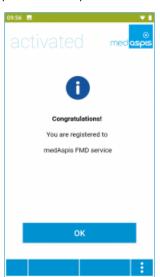
3.5 Setting up a Speed Scanner (device)

If the scanner is not in enrolment mode, please go to the application settings and click five times on the medAspis logo. The application immediately starts the teach-in process.

The scanner now scans the enrolment code from the control panel. If the scanner cannot detect the code due to possible reflections of the computer display, the "Scan" button on the Speed Scanner display can be activated. A new window opens and the enrolment code can be captured from the screen with the Speed Scanner's built-in camera.

After a second confirmation screen, a Congratulations screen appears and the Speed Scanner is connected to the system.





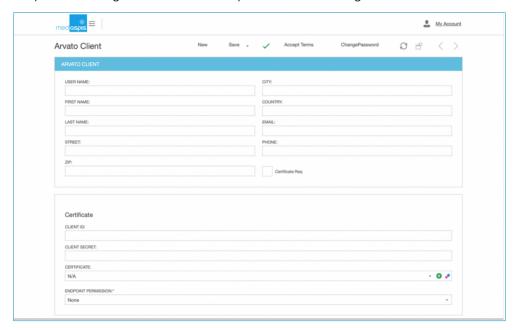
3.6 Register at NMVS

The system must be connected to the responsible NMVS in order to be able to perform the FMD tasks. Three different systems are in use in Europe. medAspis has the capability to connect to all three systems (securPharm, Arvato, SolidSoft). The necessary steps for registration are carried out in the menu item "Device Handling". Different registration steps are required for each of the three systems.



3.6.1 Access to the Arvato system

This system is used in Austria, Belgium, Cyprus, Estonia, Finland, France, Hungary, Latvia, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain and the United Kingdom (Northern Ireland).



Before this process step can be performed, the user has to be registered with his responsible NMVS and received the access data to be entered here. First, all user data is entered and then the username and initial password received from the NMVO are entered in the "Certificate" section.

The certificate is then downloaded. First, the certificate window must be opened by clicking the "plus" symbol.



The certificate file (p.12) previously provided by the NMVO is uploaded and the certificate password and password token are entered. Both data are provided by the NMVS. The certificate window is closed with OK and the entire process is completed with "Save".

Afterwards, the Arvato Terms and Conditions are confirmed in the Arvato main window and the initial password is changed. Buttons are available for both processes in the upper part of the window.



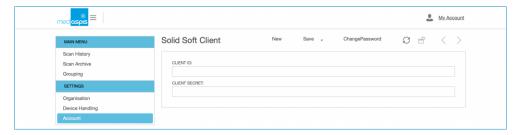
The new password is confirmed with OK. The password window closes.

The process is completed, the system is connected to the responsible NMVS.



3.6.2 Access to the Solidsoft system

This system is in use in Bulgaria, Denmark, Ireland, Iceland, Croatia, Liechtenstein, Lithuania, Sweden, Switzerland, Slovakia and the Czech Republic.

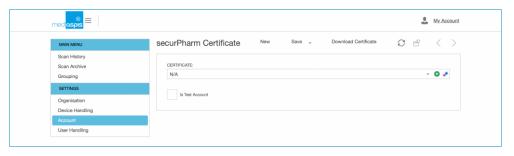


Before this process step can be performed, the user has to be registered with his responsible NMVS and received the access data to be entered here. The "Client ID" and the "Client Secret" are entered and saved with the "Save" button.

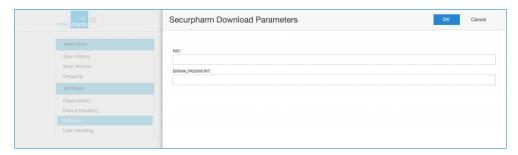
The process is completed, the system is connected to the responsible NMVS.

3.6.3 Access to the securPharm system

This system is only used in Germany.



First, the button "Download Certificate" opens a new window in which the securPharm certificate can be loaded. To download the certificate, the customer has received a so-called company number N-ID (format APOxxxxxx) and a password from NMVO. These two values are entered in the fields provided and acknowledged with "OK" at the top of the window.



The window closes again and the certificate downloaded from the NMVS in the meantime is displayed. Now the process must be saved in the securPharm main window by clicking the "Save" button at the top of the window.

3.6.3.1 Alternative registration

If you have already downloaded your certificate from NGDA yourself, you will have a file with your company number as "Name and. p12" as suffix (APOxxxx.p12).

Please click on the green plus at the input field "Certificate" first. A new window opens:



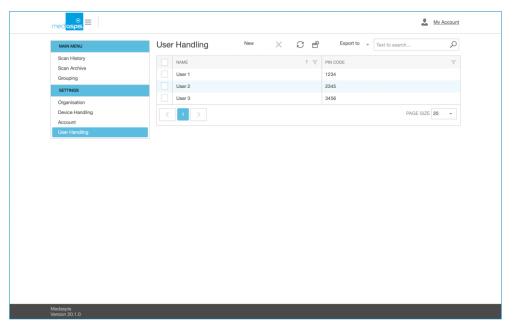


In this window the certificate can be uploaded, the corresponding password must be entered, the "PUBLIC KEY TOKEN" must remain empty.

The process is completed, the system is connected to securPharm.

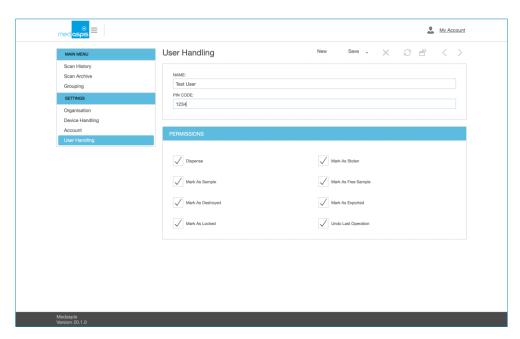
3.7 User login to the Speed Scanner

Optionally, the users of the Speed Scanners can be entered. Each time the users scan packs, the specified username is saved to that scan. The names can be displayed in the Scan History.



With the button "New" a new user can be created.





For this purpose, the username and a numeric (digit) password of any length are entered. The username appears in the "User" field in the Settings of the Speed Scanner and in the Scan History. The password is requested in the handheld device as an identity check. In addition, the permitted FMD operations can be restricted for each user.

After completion, the entries are saved with "Save".

User management is an identity control and thus a measure for organising operations. User management is not a function in the sense of system security.

3.7.1.1 Access rights

Individual usage rights can be assigned for each user. The FMD operations allowed in the "Permissions" field are displayed in the FMD menu of the hand-held scanner, the others are not offered.

3.7.1.2 In use on the Speed Scanner

A user can only use the Speed Scanner if he has entered the correct password beforehand.



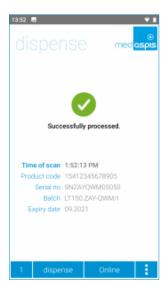


3.8 First steps

Switch on the Speed Scanner and open the "Connector+" application.



Switch on the Speed Scanner and open the "Connector+" application. You already know the unit and the application from the introduction.



Important:

If you receive a warning or an unclear message after the first scan: Please stop your first attempt and contact us immediately. It is possible that one of the credentials (user ID, password, certificate password) is incorrect. If you scan more than 5 times, your NMVS account may be blocked.

If no warnings are displayed, go to the main menu and click on the Scan History again. On this page you can see all the scans and the corresponding response from the NMVS.

Congratulations - you are now FMD compliant!

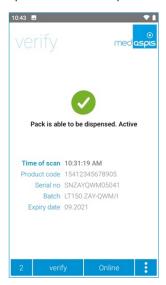


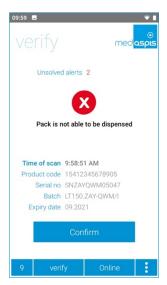
4 The Speed Scanner

The user will select the FMD option in the FMD menu of the FMD Speed Scanner application and scan the 2D Matrix Code. The information will be transferred to the NMVS and from there back to the FMD Speed Scanner. The data received from the NMVS is displayed on the screen.

In case the result is positive, the user will scan the next code. In case the result is negative the user must confirm the alert which is displayed on the screen of the FMD Speed Scanner. In both cases the scan data and the FMD result is visible in the Scan History of the Control Panel. In case of a negative result, the user confirmation is registered in the Control Panel as well.

The data can be processed further in the Control Panel. The most important function is the visualisation of the scan data. These can be filtered and exported almost as required.





4.1 Working with the Speed Scanner

First, the required FMD operation is selected via the FMD menu on the Speed Scanner. If no selection is made, the default operation is "verify".





4.1.1 Available FMD Operations

All FMD operations provided by the NMVO are applicable in the medAspis system. Some of the operations are locked for pharmacies. However, they are still displayed in the menu. If a non-permitted operation is performed, an error message is returned by the NMVS.

Menu option	wholesale	pharmacy
verify	X	x
dispense	X	Х
mark pack as destroyed	X	x
mark pack as exported	X	-
mark pack as sample	X	x
mark pack as free sample	X	-
mark pack as locked	Х	-
mark pack as stolen	X	Х
reactivate pack	X	x

4.2 Transfer the recorded code to the NMVS

The Speed Scanner immediately sends all captured records to the medAspis FMD server. Here the code is prepared and sent for processing to the NMVS. As soon as the result is sent back, the response is forwarded to the Speed Scanner.

4.2.1 Scan a 2D matrix code

The Speed Scanner captures a 2D matrix code from a medicine box and processes the captured data stream. If the scanned code does not correspond to the expected syntax in GS1 coding or PPN coding (only available in Germany), the scanning process is aborted and the message "NO FMD" is displayed. The scan attempt is also displayed in the Scan History with the same result.

4.2.2 Scan Accelerator

The Speed Scanner is able to scan faster than the NMVS can process the codes. Only one request can be made to the NMVS at a time. The unprocessed requests from the Speed Scanner go into a queue if the NMVS is slower than the Speed Scanner sends requests.

The number of records in the queue is displayed on the Speed Scanner. With fast scanning and slow NMVS, with technically undisturbed operation, up to 5 packs can be expected in the queue.

4.2.3 Processing of NMVS Response

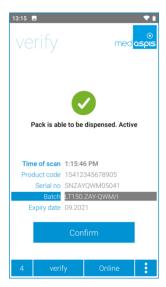
Both the Unique Identifier scanned by the 2D Matrix Code and the data set returned by the NMVS are stored completely in the data structure of the medAspis FMD system. The result is analysed and interpreted. The corresponding result is shown in the Speed Scanner display and saved in the Scan History.



4.2.4 Batch Control

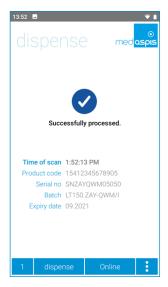
The Batch Control option can be switched on in the settings of the Speed Scanner. The Speed Scanner gives a warning if a batch or product code is scanned differently from a reference pack.

The reference pack is determined by the first scan after a counter reset in the Speed Scanner screen at the bottom left.



4.2.5 Data collection only

Packs can also be captured without the data records being automatically forwarded to the responsible NMVS. To make this state clearer, the symbol is displayed in blue.



4.3 Performing FMD Operations

This section describes the main states the system can have when processing FMD operations. Similar functions are described only once. "exported", "stolen", "sample", "free sample", "locked", "destroyed" are analogue to "dispense". In this description, "dispense" is explained in detail, the subtypes work similar.

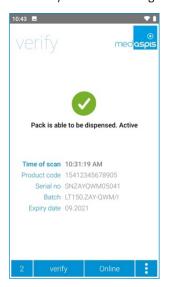


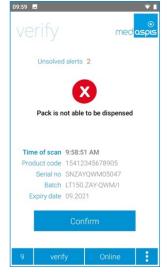
4.3.1 Verify

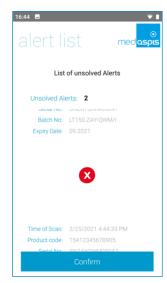
The FMD mode of the Speed Scanner is set to "verify". The 2D matrix code of a pack is scanned. A "Verify" command is sent to the responsible NMVS.

A pack can be verified as often as required. A separate line appears in the Scan History for each "Verify" command. Packs with the same serial number can be scanned as often as required and each will be found in the Scan History.

The result of a "Verify" check can be negative.







In this case, the scanner is stopped, you can no longer scan, you have to take care of the alert. This process is documented by clicking the "Confirm" button on the Speed Scanner display. Analogously, this is noted in the Scan History.

In addition, the packs concerned are secured in the Speed Scanner. The packs can be checked in the alert list. When the errors are acknowledged, the "unsolved alert" counter is reset to zero.

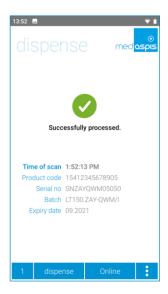
4.3.2 Dispense

The FMD mode of the Speed Scanner is set to "dispense". The 2D matrix code of a pack is scanned. A "Dispense" command is sent to the responsible NMVS. The result can be positive or negative, just like "verify" and all other FMD operations.

The command "dispense" sets the status of the pack from "active" to "inactive". A pack that is set "inactive" cannot be dispensed again.

A separate line appears in the Scan History for each Dispense command.



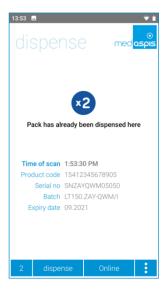


4.3.3 Double Dispense

Redispensing an already inactive pack will result in an NMVS error. This error may occurs very often because packs are dispensed several times due to carelessness.

Under certain conditions, the medAspis system recognises a dispensing as a duplicate and does not send it again to the NMVS. Instead, the result of the previous dispense is displayed again, but with the "Double Dispense" icon. The same response is also displayed in the Scan History, again with the Double Dispense icon.

The condition for detecting a double is that the same pack has been deactivated with the same FMD command within the last 10 minutes.



4.3.4 Double Dispense Filter is switched off in certain situations

The Double Dispense Filter does not send the same FMD operation (Disable, Export, Stolen, Destroy, Probe, etc.) to the NMVS for rechecking for a set period of time (10 minutes in the default or two hours in Alert Guard).

However, there are results for which this time delay is a disadvantage. For example, if the NMVS system is unavailable for a short time, the double-dispense filter is turned off and another FMD operation is possible immediately.



The double-dispense filter is also switched off for login operations (login, password entry, etc.).

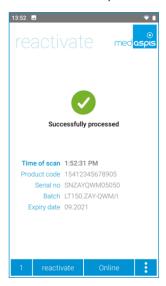
4.3.5 Reactivate

The FMD menu of the Speed Scanner is set to "reactivate". The 2D matrix code of a pack is scanned. A reactivation command is sent to the responsible NMVS. It is not necessary to specify the original FMD operation to be reset now. This attribute, which is necessary for the NMVS, is automatically added to the reactivation command by medAspis system.

Excluded from this are the statuses "marked as stolen" and "marked as destroyed". The NMVS system don't allow to reactivate those statuses.

Reactivation resets the status of the pack from "inactive" to "active". For various reasons, this operation can be negatively acknowledged. Then an error message appears.

The reactivation is displayed as a separate line in the Scan History.



4.3.6 Manual Entry

If a 2D matrix code cannot be scanned by the scanner, the data can be entered manually. To do this, the predefined fields must be filled in and the required FMD operation must be specified.

If an expiry date has only year and month, the day in the display is either left blank or filled with 0 (zero).

The NMVS response appears again on the main screen of the FMD Speed Scanner.

In the Scan History, the manual display is not specially marked. The FMD command resulting from the manual input is displayed exactly as if it had been generated by the scanner.





4.3.7 Offline Mode

A permanent internet connection from the hand-held device to the medAspis server is necessary for the unrestricted function of the Lean FMD system. All scanned data records are immediately sent from the handheld device to the server, where further processing takes place.

If the internet fails, this processing is disrupted. There are many reasons for a broken connection: The handheld scanner or the server are not working correctly, a malfunction at the internet provider, technical faults or changed settings in the local wi-fi router.

In such cases, the hand-held device indicates the loss of the Internet connection and records all data sets. The offline status and the number of data records temporarily stored in the device are displayed in the field at the bottom right.



As soon as the Internet connection is re-established, all stored data sets are automatically transferred to the server.

ATTENTION: The data is not processed on the server immediately. Manual intervention is required to perform the originally desired FMD operations.

4.4 The Speed Scanners settings

Various settings can be made on the Speed Scanner.



The light blue box contains information about the account, the scanner name and the current user of the device.

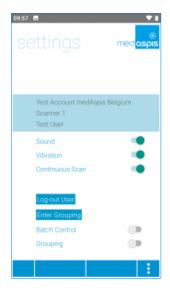
The three switches below control the scanner unit. You can switch the sound and vibration on and off separately. In continuous mode, the scanner is switched on permanently using the side buttons or the pistol grip. 2D matrix codes are now continuously captured until the scanner is manually switched off again. If the continuous mode is switched off, 2D Matrix Code can only be scanned one at a time.

"Log Out User" logs out the current user. You have to register again for the next service.

"Enter Grouping" forces the entry of a new grouping.

"Batch Control" switches on the automatic batch control.

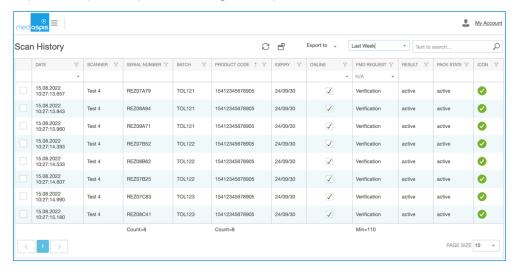
"Grouping" switches on the grouping function.





5 The Scan History

The Scan History shows all data sets acquired with the Speed Scanners and the corresponding result of the NMVS. The data is stored permanently. It is not possible to change or manipulate the data itself.



For each scan, the time stamp, the pack information (product code, serial number, batch number, expiry date), the online status and the FMD result including the current pack status are displayed. Each entry is displayed with the same icon that was previously visible in the Speed Scanner. If the user clicks the confirmation button after a negative result, this is also logged in the Scan History.

The time stamp is the time of the medAspis FMD server. The time stamps of the handheld devices are not logged. Thus, the time recording cannot be manipulated by changing the system time in the Speed Scanner units.

After 40 days, the Scan History entries are transferred to the Scan History Archive for performance reasons. The Scan Archive has the same functionality as the Scan History.

There are two icons to control the scan history and all other views:



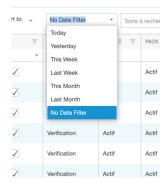
Clicking on this symbol reloads the contents of a table. This function is useful if new data has been created with a scanner that has not yet been displayed.



The view of tables can be changed. By clicking on this symbol, all tables can be reset to the original view.

5.1 Working with the Scan History

The Scan History always starts with the preset filter "Today", so only the scans from the same day are displayed. The list may then be empty if no scans have been performed on that day. The desired period can be selected by simply changing the drop-down menu. The setting "No Date Filter" shows all entries in the scan history. If other time filters are to be used, the filtering of the date in the date column is available at any time.





5.1.1 Sort data

Sorting each individual column of the Scan History table is possible by clicking on the respective column header. The sorting is indicated by an arrow symbol to the right of the column title. Clicking again reverses the sort order.

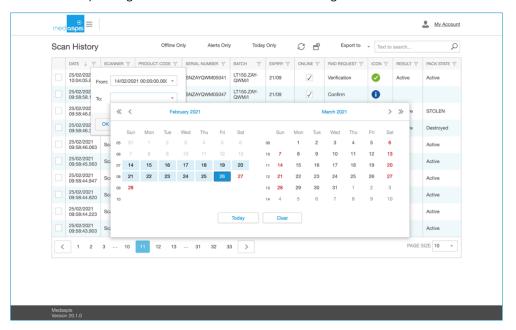
The default setting is sorting by date. The most recent entry is displayed at the top.

5.1.2 General filters

The data sets can be filtered as required, all filters can be combined. Each column has a funnel symbol next to the heading. By clicking on the funnel symbol, a window is displayed with which a filtering of the corresponding column can be carried out.

The date can be narrowed down with start and end date. A specific serial number can be filtered, a specific expiry date, a specific pack status, etc.

Set filters can be deleted by clicking on the "Clear" function at the bottom right of the screen.

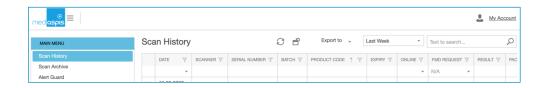


5.1.3 Search functions in the table

Directly under the table headings, you will find a direct search function for most columns. In the case of predefined column contents, the contents can be selected directly via an expanding context menu.

Combinations of filters in different columns are possible. The selected search filters are summarised in text form in the sub-line and can be completely cleared again at any time by clicking on the word "clear".

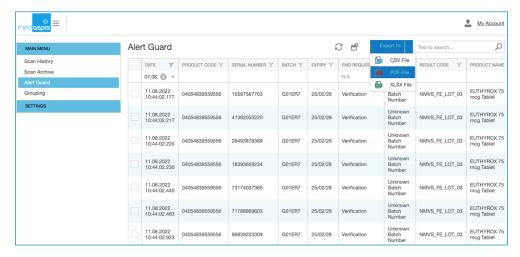
Attention: Only those columns can be searched, sorted or filtered for which this option has a practical use. Otherwise, the column search is not available.



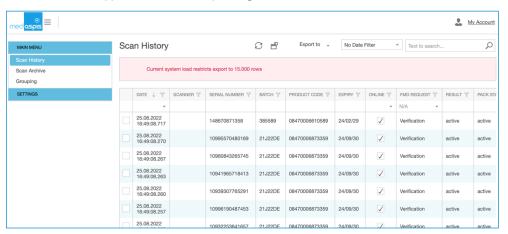


5.1.4 Export data

The selected and filtered data can be exported. All displayed parameters (displayed columns) and entries (displayed rows) can be exported from the system to CSV, XLS, XLSX and pdf formats. The data is provided via the download function of the browser.



If the number of records to be downloaded exceeds the technical capacity of the system, the export will not be carried out; instead, a short note will appear with the corresponding information.



5.1.5 Display of additional Information

All additional information can be displayed for each individual scan by clicking on the respective line.

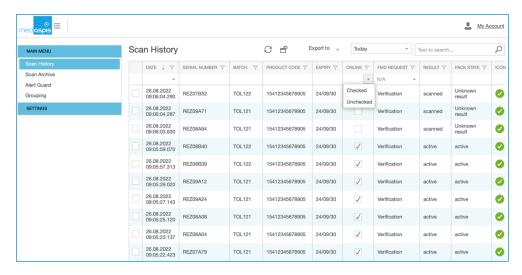




5.1.6 Offline Mode

If the handheld device does not have a direct Internet connection during operation, the data is temporarily stored for this time and immediately uploaded to the server as soon as the Internet connection is available again.

The data is displayed in the scan history and marked as offline (not online). With the filter functionality of the table column, all offline scans can be found and displayed immediately.



It is not known to the system whether these offline scans should be sent to the NMVS or not. Only the user knows if another scan has been made in the meantime or if the offline scan was made so long ago that it has been obsolete in the meantime.



For this reason, the entries marked as offline in the scan history must be activated individually and manually. To do this, click on the relevant line and scan the 2D matrix code with a hand scanner. With this information, the content concerned can be processed. The scan creates a new entry in the scan history.

If there are several offline entries to be processed, you can easily switch to the next entry in the detail view by clicking the next button. If the offline filter was previously activated, only offline scans are included in the detail views.

5.1.7 The context menu

The context menu can be opened by clicking the right mouse button on the table heading. The following functions can be started:

Sort Ascending, Sort Descending: The selected column can be displayed sorted.

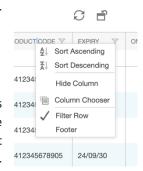
Hide Column: The selected column is removed from the table.

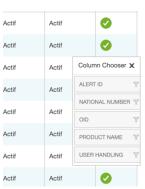
Column Chooser: An additional menu is displayed on the right side of the page. All columns are listed that can be displayed in addition to the existing overview. To activate one of these columns, move the desired column title from the displayed list with the mouse and insert it into the table at the desired position. The table will then always appear in this modified view.

Filter Row: With this function the search field of the columns can be shown or hidden.

Footer: An additional blank line is displayed below the displayed rows. In this line, another context menu can be activated by clicking the right mouse button again. In this menu, for example, a counting function can be activated. The number of lines currently selected is then displayed.







5.2 Settings of the Scan History

5.2.1 Number of records displayed

10, 20, 50, 100 or 200 lines can be displayed per page. The setting can be made through a drop-down menu at the bottom right edge.

5.2.2 Detailed information to a Scan

More information is available for each record than is shown in the default setting of the Scan History. Values shown in the standard display are marked with x:

DATE x time and date of scan (server time)

SCANNER x name of scanner

PRODUCT CODE x product code of scanned pack
SERIAL NUMBER x serial number of scanned pack

BATCH x batch of scanned pack EXPIRY x expiry date of scanned pack



ONLINE x yes / no, pack scanned while Speed Scanner was online

FMD REQUEST x requested FMD operation to the NMVS ICON x icon of result (full list in attachment)

RESULT x text message of the result (full list in download area)

PACK STATE x status of the pack after the FMD operation was performed

PRODUCT NAME full name of the scanned product (optional)

MAH NAME name of MAH (optional)

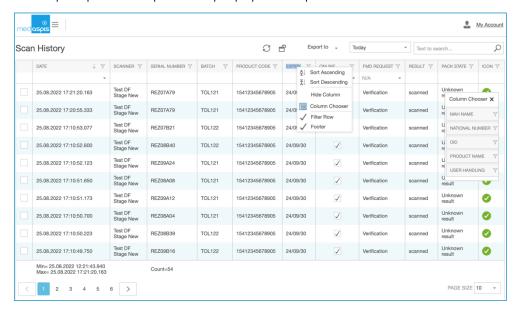
NATIONAL NUMBER national health reimbursement number (optional)

USER HANDLING name of user who scanned the pack

OID A unique key with which the record can be identified.

5.2.3 Visible Columns in the Scan History

To change the display of the Scan History, right-click on the table header. A context-sensitive menu opens. Two menu items control the table view. "Hide Column" removes a selected column from the view. "Column Chooser" opens another window that shows all parameters not previously displayed. Use the mouse to drag the required information to the top of the table. The required parameter is permanently displayed at this point.





6 Performing Grouping Operations

The medAspis system is able to process individual queries but can also work with groupings of packs. These groupings can be processed as a whole.

6.1 Groupings

Groupings are a list of packs that are grouped together under one key.

6.1.1 Grouping on the Speed Scanner

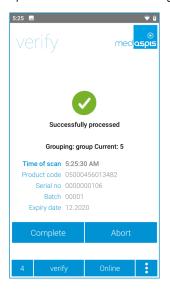
In the menu of the handheld device, the Grouping button is clicked. The device then expects the name of a grouping as the first input. This can be entered using the keyboard or a barcode is recorded. Alternatively, all machine-readable codes set in the handset menu will work, for example QR codes or 2D matrix codes.

The standard screen of the Speed Scanner changes. Additional information is provided. A line below the icon shows the name of the grouping and the number of packs already scanned into this group.

In addition, there are two buttons to complete or cancel the grouping. When the grouping is completed, this must still be confirmed with a "Confirm" button. The grouping can then be seen in the control panel under the menu item "Grouping".

If Batch Control is switched on, no packs with a different batch or product number are included in the grouping.

The entire FMD functionality is retained. FMD alert messages are always treated with top priority.

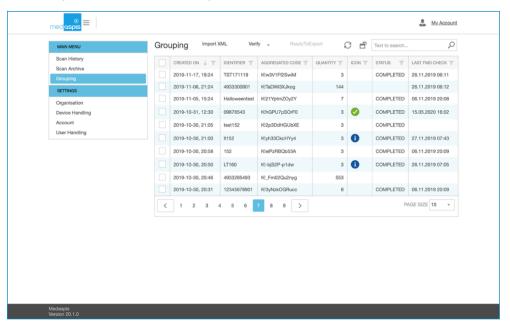






6.1.2 Grouping on the Control Panel

Groupings are called up via the menu in the control panel.



Various parameters are given for each grouping. Values shown in the standard display are marked with x:

IDENTIFIER x The name of the grouping chosen by the user.

QUANTITY x The number of packs included

ICON x The icon of the last FMD operation on the grouping.

AGGREGATION CODE x The system-assigned name (primary key) of the grouping.

STATUS x The current status of the grouping

LAST FMD CHECK x The time of the last FMD operation performed.

MODIFIED ON The last time at which the grouping was processed

FMD operations can be performed on groupings. With the check boxes in the first column, groupings can be selected. The choices in the drop-down menu above are VERIFY, DISPENSE and EXPORT (see chapter 6.2).

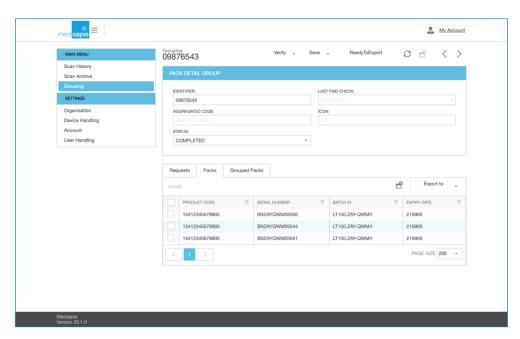
Groupings can also be created by importing XML files with pack information. The XML format is described in Appendix 4.

Clicking on a line displays individual information of individual groupings.

6.1.3 View of a Single Grouping

From the list of groupings, individual groupings can be called up by clicking on the respective line of the overview.





This view provides some general information about the grouping. The name and status of the grouping can be changed.

There are three tabs that contain further information of the grouping.

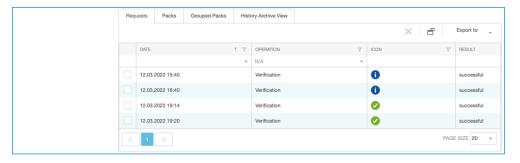
1. tab "Requests": All previous FMD operations on the entire grouping are displayed. The following parameters are displayed:

OPERATION The selected FMD operation

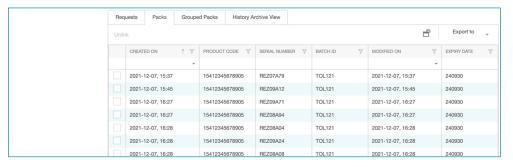
DATE The date of the operation

ICON The icon of the result

RESULT The result of the FMD operation

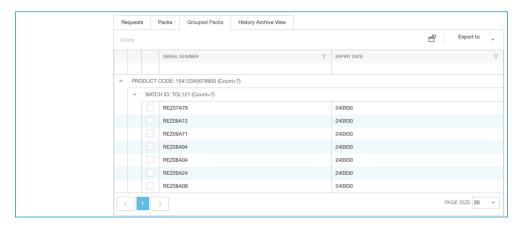


2. tab "Packs": A list of all packs included. The display corresponds to the Scan History display. The display of the parameters can be changed as in the Scan History.



3. tab: "Grouped Packs": A list of all contained packs sorted by different product codes and batches. If a grouping is not homogeneous, you can see it here at a glance.





4. tab: "History View": In the groupings, the contained packs were previously displayed, but not the respective FMD status. With this release, the associated scan data is displayed for each group. This includes all attributes that can also be seen in the scan history.

If the scanned packs have been transferred to the Scan Archive in the meantime, a reference to the archive is automatically created. If packs are partly in the scan history and partly in the archive, both assignments are displayed.



6.2 FMD Operations on groupings

An FMD operation on the grouping is initiated with the pull-down button at the top of the screen. VERIFY, DISPENSE and EXPORT are available. The FMD operation is applied to all packs in the grouping.

6.2.1 Perform FMD operations on groupings

A grouping is applied in the so-called "bulk mode". The entire content of the grouping is transferred to the NMVS in a single step. Processing takes some time, the result is not returned but is waiting for retrieval on the NMVS server.

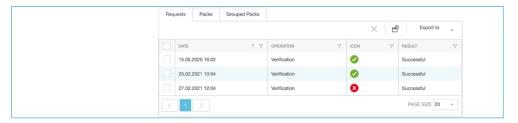
The medAspis system checks at increasing intervals whether the processing of the bulks is ready. As long as processing is not completed on the NMVS side, a blue icon with a rotated arrow is displayed.



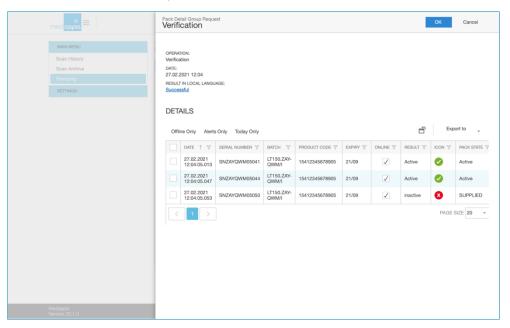
Whether processing is finished on the NMVS side can be determined by clicking the reload button. As soon as the data processing on the NMVS side is finished and can be retrieved, this icon is replaced by the result icon. The result of the bulk query then appears in the RESULT column and the corresponding green or red icon. The icon is a representation of the



most negative single result of the packs. If only one pack has a negative result, the entire bulk is marked with the red cross.



More detailed information on the bulk operation is provided by clicking on the respective line. The immediately opening sub-window shows the packs contained in the grouping together with their respective FMD result. The view and functionality are the same as in the Scan History.



6.2.2 Special features of bulk operation in the Arvato system

Arvato handles the processing of bulk operations differently from the other two providers Solidsoft and securPharm in two respects:

Exception homogeneous bulks: Arvato allows wholesalers to process homogeneous bulks only. In these bulks, the product codes, batches and expiry dates must be the same for all packs. Only the serial number may vary. Requests with mixed bulks are returned as an error with no results reported on individual packs.

Exception: Return of individual pack results: As a rule, bulk operations return an individual pack result for each pack included. There is one exception to this rule at Arvato: If all the packs contained in a verify bulk operation have a positive result, an individual result is not delivered for each pack, but only for the entire bulk. There is only one result representing of all the packs included.

6.3 Working with Groupings

Groupings are usually used to apply FMD operations to existing business processes. Either packs of business processes such as deliveries are processed together, or packs in distribution units such as cartons or pallets are grouped together.



6.3.1 Status of a Grouping

Groupings can have different statuses. The status can be used to describe the state of the grouping. Example: Packs can still be added to an open grouping, a grouping with the status "Completed" can no longer be changed.

UNDEFINED default value before usage

OPEN a grouping is on the way to get established
COMPLETED a grouping is finished and able to be used
VERIFIED a grouping is checked the first time

EXPORT an aggregation is exported to use by third party

6.4 Aggregation as a special form of grouping

Aggregations are sub-forms of groupings. Aggregations have all the attributes of groupings but no user-assigned name and they can be used more flexibly.

6.4.1 Aggregation Code as primary key of any Grouping

Groupings always have a primary key (unique name). In medAspis, the primary key is a 64bit long unique identifier in base-64 notation. In this notation, the primary key is formed from letters, numbers and common special characters. medAspis uses the characters: A-Z, a-z, 0-9, + and -. Prefixed with a "K!", an example is "K!E9j-I9S4TVI".



Each grouping – no matter what name the user assigns – has a primary key formed in this way. The reason: Within the medAspis system, all groupings must be clearly identifiable. However, it may be that different customers use the same delivery note numbers for their grouping, for example. To be sure that all groupings can always be reliably

identified and assigned in the system, the primary key is the aggregation code automatically generated for each grouping. This can never be changed or manipulated.

6.4.2 Hierarchical structure of aggregates

Using the aggregation codes as primary keys, groupings can be organised hierarchically. Aggregations can be part of a super-aggregation. This hierarchical relationship can take place in as many levels as required.

6.4.3 Exporting aggregations

Aggregations can be made visible to third parties. If the status of an aggregation is set to EXPORT, the aggregation is visible for others and can be taken over into the own data structure. Aggregations are passed on, for example, by sticking the aggregation code on an aggregated box. The receiver sees the code, scans it and has taken the data into its own data structure.

6.4.4 Aggregation codes on stickers

For easy processing of aggregations, medAspis provides lists with aggregation numbers to its customers.



7 Active Alert Management

The medAspis active Alert Management effectively protects you from false alarms and supports you in the few remaining suspicious cases. Once detected, false alarms reduce the burden of documentation and keep the operational process running. The few remaining cases are reliably identified, processed and documented. The effort required for compliance assurance in serialisation is significantly reduced.

The Alert Guard function is displayed in the main menu. Alert Guard is an additional service for which a fee is charged and which is only activated selectively.

7.1 Preventing false alarms with Alert Protect

The majority of false alarms occur when medicine packs are accidentally deactivated more than once. Double deactivations inevitably lead to falsification alerts that are forwarded to the authorities. medAspis consistently prevents these false alarms.

7.1.1 Double Dispense Filter

The original double dispense filter covers a period of 10 minutes. This period is increased to two hours.

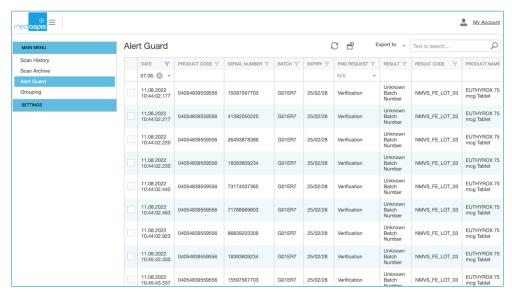
Within this period, the same FMD operation (Disable, Export, Stolen, Destroy, Sample, etc.) will not be transmitted to the NMVS for a second verification.

7.2 Solve and document suspicious cases with Alert Guard

Alle Fälschungsverdachtsfälle werden im System erkannt und kenntlich gemacht.

7.2.1 Alert Overview

All critical cases are clearly presented. Instructions for action are available for scanning staff and supervisors.



DATE x time and date of scan (server time)
PRODUCT CODE x product code of scanned pack

SERIAL NUMBER x serial number of scanned pack



BATCH x batch of scanned pack

EXPIRY x expiry date of scanned pack

FMD REQUEST x requested FMD operation to the NMVS

RESULT x text message of the result (full list in download area)

RESULT CODE x The alert code specified by the NMVS (e.g. SP-201 or NMVS_LOT_03).

PRODUCT NAME full name of the scanned product (optional)

MAH NAME name of MAH (optional)

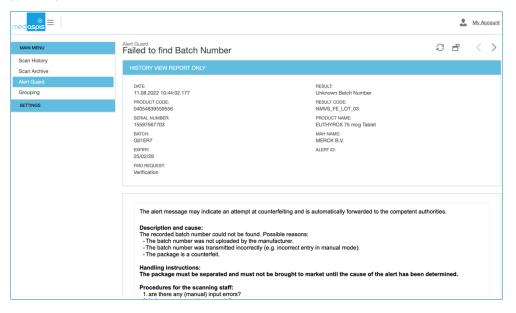
NATIONAL NUMBER national health reimbursement number (optional)

OID A unique key with which the record can be identified.

PACK STATE status of the pack after the FMD operation was performed

USER HANDLING name of user who scanned the pack

Clicking on a line displays more details about the falsification alert, including detailed instructions for the scanning staff and the responsible person.



7.2.2 Alert Guard Report

A PDF report can be generated from the currently displayed alert overview at any time using the export function. This report shows the most important attributes of the suspected falsification alert. In a separate field, comments can be made on the specific case.



				med	Spis
Alert Guard F	Report				
11.08.2022 10:46:14	Failed to find Batch Number		FMD Request	Verification	
Product Code Serial Number Batch Expiry			MERCK B.V. EUTHYROX 75 i	mcg Tablet	
Alert Code	NMVS_FE_LOT_03 - Unknown Batch Nu	ımber			
Description	The package must be separated and must been determined. Photograph the 2D mainstructions of your NMVO.				
Measure				Completed	
11.08.2022 10:44:02	Failed to find Batch Number		FMD Request	Verification	
Product Code Serial Number Batch Expiry	04054839559556 41392050220 G01ER7 25/02/28		MERCK B.V. EUTHYROX 75 r	mcg Tablet	
	NMVS_FE_LOT_03 - Unknown Batch Nu	ımber			
Alert Code					
Alert Code Description	The package must be separated and must been determined. Photograph the 2D mainstructions of your NMVO.	st not be placed			
	The package must be separated and must been determined. Photograph the 2D ma	st not be placed			



8 Offline Processing

In general, all scans captured with the FMD Speed Scanner are immediately forwarded to the FMD server and processed there. The records are then checked at the NMVS and the check result is displayed in the scan history and on the FMD Speed Scanner.

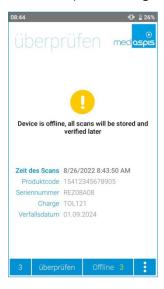
Unfortunately, it cannot be avoided that the internet connection between the FMD Speed Scanner and the FMD server is disturbed. This can have various reasons:

- The capturing software on the FMD Speed Scanner is not working properly or the FMD Server is not responding.
- The technical equipment on site is disturbed.
- The FMD Speed Scanner's connection to the Internet is temporarily disrupted.

The most common cause is an often only short interruption to the Internet. This can happen if not all areas of the warehouse are covered by the local router or if scanning has to take place in a location that is unsuitable for wireless transmission, e.g. in the cold store.

8.1 On the FMD Speed Scanner

If the connection to the Internet is lost, the FMD Speed Scanner detects this immediately. On the handheld device, the status changes to Offline (visible in the bottom line) and a yellow warning icon with a short explanatory text appears.



Nevertheless, the FMD Speed Scanner remains operational. Data is recorded, work does not have to be interrupted. All codes captured during the offline phase are saved in the handheld device itself; under no circumstances data records are lost. The number of codes captured in this phase is shown in yellow in the bottom bar.

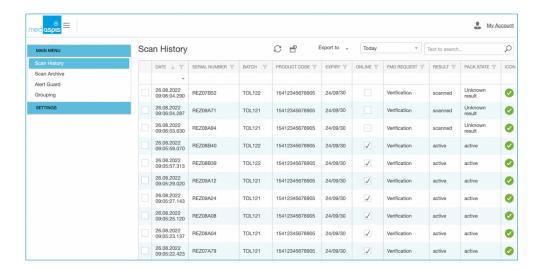
However, the operational functionality is limited. As there is no access to the internet, the data cannot be transferred to the FMD server and direct processing by the responsible NMVS cannot take place either.

As soon as the Internet connection is re-established, all data records recorded and temporarily stored in the FMD Speed Scanner are transferred to the server. Depending on the amount of data, this may take a while.

8.2 Further Processing in the Scan History

All data records transferred by the handheld device after the offline phase is ended are displayed in the scan history. This data can be recognised by the missing ticks in the ONLINE column and the status of the pack. As there is no information about the status of the pack from the NMVS, the status is marked as unknown.

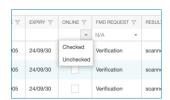




ATTENTION: The FMD operations recorded during the offline phase are NOT executed. Since it is not known how long the unit was offline and because a replacement scan may have already been performed, the subsequent execution of FMD operations is left to the user.

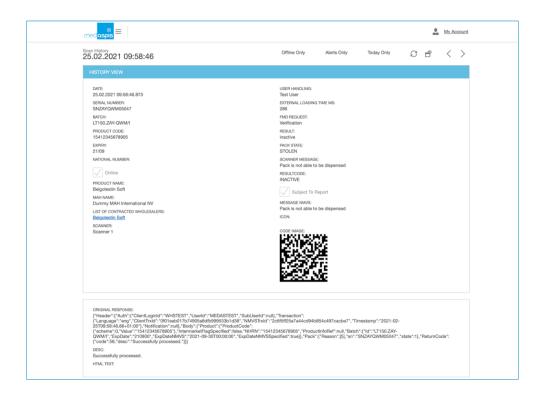
If the entries marked as offline are sent to the NMVS, this must be done by scanning them again. However, the packs are no longer needed for this.

First filter the packs marked as offline.



Click the first filtered line. The detailed data for this scan will appear. Among other things, you will see a 2D matrix code. This code can be scanned with the FMD Speed Scanner as if scanning from the pack. Scan this code with the desired FMD operation. The scan results in a new entry in the Scan History.





The navigation arrows in the top right-hand corner can be used to jump immediately to the detail view of the next offline pack. These arrows are active until the last offline pack has been reached.



9 Attachment

9.1 Updating the Speed Scannner via F-Droid

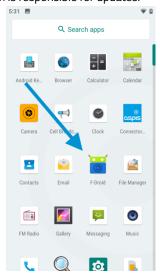
9.1.1 Manual Software Updating

medAspis will periodically issue updated versions of the application software. The system continuously checks for updates and installs them automatically. These automatic installations may – very rarely – not succeed, meaning the medAspis application update needs to be performed manually. Please see below the instructions for manual software updating.

On the screen, just swipe up the screen and you open the list of programs on the device (Android users will be very familiar with this).



Select the application 'F-Droid'. This program is responsible for updates.

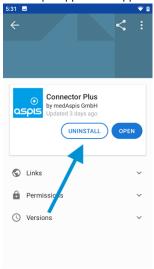


You should see the medAspis Connector+ application on the screen; if not, press 'Latest' on the bottom row. If you still do not see the medAspis Connector Plus application, try the search function on the bottom right and search for 'medAspis'. The application should be visible.

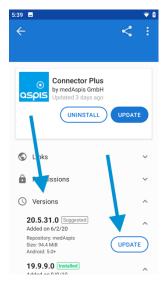




Tap the Connector+ application; details of the medAspis application appear.



You will be asked if you want to uninstall or open the medAspis application. Please choose to uninstall and complete the de-installation process. Do not worry, the application will not be lost; a fresh version will be reloaded.





Please click on 'Versions'. This shows several versions to choose from. Touch the top version labelled 'suggested' (this is the most up-to-date version).

Touch 'Install' and follow the installation instructions.

9.1.2 Automated Software Updating

Open the F-Droid (instructions are similar to Manual Software Updating) and click on Settings. A page will open that will be like the one in the picture below. Scroll down to see the Updates.



Configure the Automatic Updating similar to the settings in the picture. Make sure that the Speed Scanner remains connected to the Internet. Once a new release of software will be available, the F-Droid will register it and update the application.

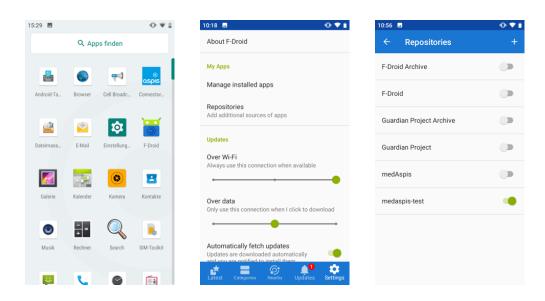


9.1.3 Installation of test versions of the medAspis App

To use a test instance of the software, the existing app must be deleted and a test instance of the Connector+ software must be loaded from a test repository in F-Droid. The Connector+ app for the productive system is in the "medAspis" repository, whereas the test app is in "medAspis staging".

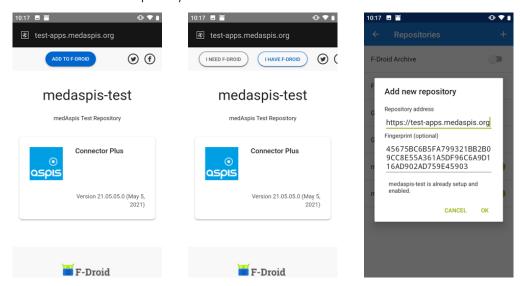


Start F-Droid from the Android interface of the handheld scanner and go to the settings (bottom right in the F-Droid app). After clicking on the "Repositories" button, a list of all active repositories appears. In any case, there is a repository "medAspis", the repository "medAspis staging F-Droid Repository" could also appear. This staging repository must be activated, the "medAspis" repository must be deactivated.



If the test repository has not yet been created, the following steps must be carried out in the browser of the handheld device:

Open the browser of the Speed Scanner and enter this URL https://apps.staging.medaspis.org. A web page from F-Droid appears. Please click on the button "ADD TO F-DROID" in the upper part of the window. Another window will open immediately. Please click on the button "I HAVE F-DROID". On the page that then appears, please confirm the displayed data with the OK button. The test repository is now created on F-Droid.

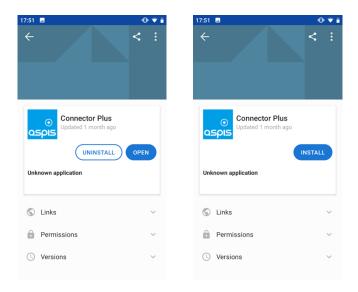


Switch back to F-Droid, go to the settings and click on "Repositories". Now you can see all the data directories from which new applications can be loaded. To be sure that only the test application is loaded, please switch on the test repository "medaspis test" and switch off the productive repository "medAspis". Switch back to the main F-Droid interface. Click



"Latest" in the menu at the bottom left. You may already see the medAspis app now. If not, please use the search button on the bottom right. Type "medAspis" in the search field. The app appears and can be clicked on.

First, please click the UNINSTALL button to delete the existing app. Don't worry, in the next step the app will be loaded again. Please follow the further instructions of the uninstall process. As the next step, please follow the instructions to install the new software.



The test software is now installed, and the handheld device can be used in test mode. Please decide how you want to test the new app. A test panel is available for a complete test, but the app also works in the productive environment.

You can reach the test panel at https://panel.staging.medAspis.org, the productive environment can be found as usual at https://panel.medAspis.org.

You must activate the app in the respective preferred environment. If your device is still connected to the system after installing the new app, please press the logo 5 times in succession in the app settings. The device then switches to enrolment mode, in which the device can be enrolled in a new environment.

Now start the panel in the productive or test environment. If you use the test environment, you should know that the packs scanned in this environment cannot later be transferred to the productive environment. However, the test environment is also connected to your NMVS. If you want to avoid this, please ask your NMVO for a test environment and reenter the access data.

Attention: It is important to follow the de-installation and re-installation routine because the originally loaded productive application must be deleted before the test application can be installed.

Attention: Please do not forget to load a production app again after testing the app in order to continue with productive work. To do this, you must switch off the test repository "medaspis-test" and switch on the productive repository "medAspis" in the same way as described above. Again, you must delete the current test app and reload the Connector+ app that is then offered. Make sure that the codes scanned with the new app appear under https://panel.medAspis.com in the productive environment If this is not the case, please repeat the installation procedure.



9.1.4 Renewal of a certificate

From time to time, the access certificates must be renewed. The procedures differ depending on the Blueprint provider:

securPharm:

The renewal of your certificate is requested via the NGDA portal. You will then receive a letter from the NGDA containing a TAN that you can now use in your medAspis Control Panel.

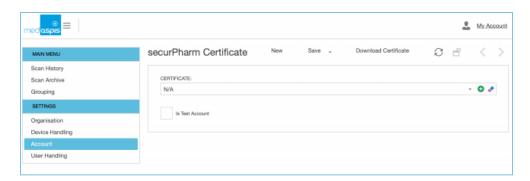
The required field can be found in the menu in the Control Panel under the securPharm Access tab. Click on "Download certificate" to open a window in which you will be asked for your NID (establishment number, beginning with APO) and a one-time password. Please enter the password you received from the NGDA and click OK. The certificate is uploaded automatically.

Save the changes and the new certificate is activated and connected to your account.

If you have already downloaded the certificate (.p12 file) via the NGDA portal, you can also include it directly as a file in your ControlPanel.

To do this, please click on the green "+" symbol under ControlPanel/securPharm Access, "search" your PC for the certificate and enter the certificate password in the "Private Key Password" column. The column "Public Key Token" should remain empty.

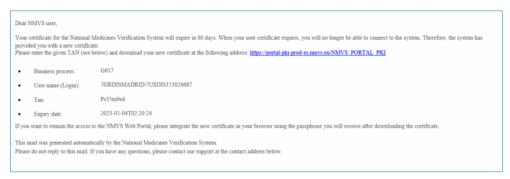
"Save" the changes and the new certificate is activated and connected to your account.



Please do not forget to complete the process by pressing the SAVE button.

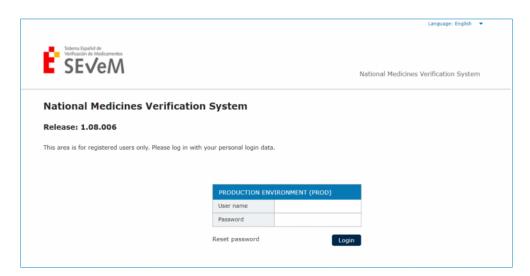
Arvato:

You must request a new certificate from your NMVO. In the example presented here, this is SEVeM, the Spanish NMVO. In this case, the response is a user name, a TAN code and a URL.

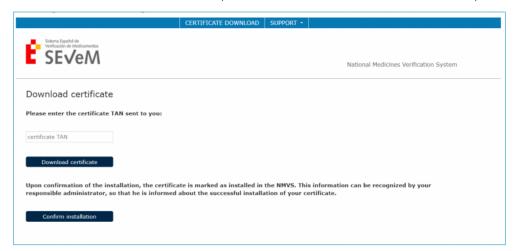


Please go to this URL and log in with the username and password you already have. Attention: The username consists of two parts separated by a "/". Here: "7GRDISCASTILLALEON/7USDIS158415304")

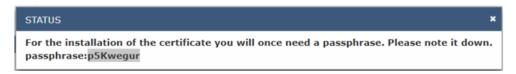




Please download the certificate from the website of your NMVO. You will need the TAN from the letter you received.



During the loading process, another window opens with a password. Please take a screenshot of this window or write down this password.

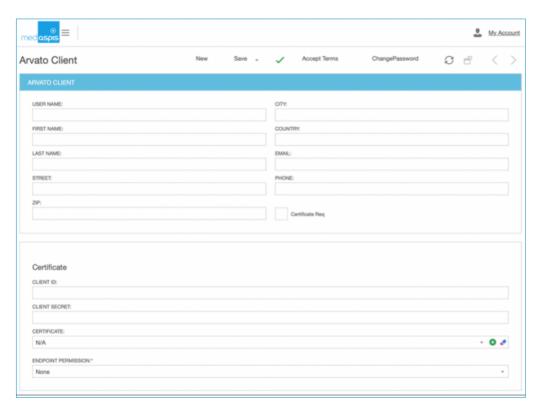


Once this process is complete, the certificate will be on your computer as a file. In the directory you specified for the download or in the standard directory for downloads from the Internet.

The best thing to do is to edit the file name of the certificate and append the current year. So that you don't get confused with the different certificates in the coming years.

From now on, the process continues in the medAspis Control Panel. Please go to the Account tab in the menu.

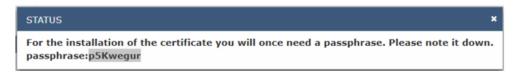




The previous certificate is entered under the heading "certificate". Please press the green plus sign. Another window opens, the certificate can be uploaded from the directory of your computer



Use the Browse button to start the upload process. Once the certificate has been found and confirmed, please enter the password you received. Reminder: This password was provided to you by your NMVO:



Enter the password. The Token field remains empty.

Please do not forget to end the process by pressing the SAVE button at the top of the screen. You have now set up your new certificate.



9.2 Attachment: Icons

The symbols used in the system follow a colour scheme:

9.2.1.1 NMVS colours:

The symbols of the NMVS answers are shown in the familiar traffic light colours green, yellow and red.

OK Warning Alert

9.2.1.2 System colours:

Other symbols for additional system information of the medAspis system are in blue.





9.3 Attachment: XML format for importing pack data

XML files with the following sample format can be imported.